REMARKS

Claims 1-21 are currently pending in the application. Only Claims 1 and 12 are in independent form.

Applicants wish to express their appreciation for the courtesies extended to Applicants' attorney Amy Rinaldo, during an interview conducted August 15, 2002, and Kenneth Kohn and Andrew Parial, during a personal interview conducted October 10, 2002. During the personal interview, a limitation to claim 1 was proposed to overcome the cited prior art references.

Claims 1-11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Eibl et al. patent. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Eibl et al. patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The presently pending claims have been amended to specifically recite that the probe is removed from the reaction vessel in order to stop the reaction without a washing step. This is specifically set forth in the specification on page 7, lines 12-18, and page 13, lines 12 and 13, and throughout the specification. In the prior art reaction vessels, there was a required treatment step or washing step in order to stop the reaction. The benefit of the present invention is that no washing step is required. All that is required is that the probe be removed from the reaction vessel and enzymatic activity can then be measured. The claims have been amended in order to further prosecution to recite that enzymatic activity is being measured. The prior art reference disclosed determining the presence of an antibody in a sample. There is no disclosure or suggestion in the prior art reference that the mere removal of the probe from the vessel is sufficient to stop the reaction. Instead, a further step is required, thereby necessitating further reagents to be utilized. The benefit of the present invention is that it simplifies all of the reactions required by only requiring that

the probe be removed from the vessel. This is a benefit over the prior art and an improvement thereon.

The Office Action states that the Eibl et al. patent discloses elongated elements such as "platelets" or pins, which are secured to a holding band in a carrier and that are insertable into the recesses of a microtiter plate containing samples to be assayed. Further, the Office Action states that various competitive assay formats are taught using an antigen or antibody bound to the elements and a labeled antigen or antibody added to the sample. Therefore, the Office Action concludes that the Eibl et al. patent teaches the carrier for the avoidance of complicated separating and washing procedures as are found in prior art assays performed with coated vessels, such as tubes. It is undisputed that the Eibl et al. patent discloses the use of elements that are secured to a holding band in a carrier that is insertable into the recesses of a microtiter plate containing samples to be assayed. However, when read more specifically, the Eibl et al. patent teaches an assay that utilizes:

> ". . . a solution of the radioactively labeled antibody [that] is added to the sample to be examined for a content of antigen or antibody, and then a solid carrier loaded with unlabeled antigen is contacted with the sample liquid, whereupon after washing of the carrier, the radioactivity of the carrier is measured."

Column 2, lines 28-33, of the Eibl et al. patent. In other words, the Eibl et al. patent teaches an assay kit, but still requires a washing step in order to measure the radioactivity of the carrier.

While the Eibl et al. patent discloses an assay kit with fewer steps required for performing the assay, it still requires utilizing washing procedures in order for the assay to perform properly. This is in contradistinction with the method of the presently pending claims, which instead do not require a washing step.

It was previously thought by those of skill in the art that washing was

required in order to stop the reaction; i.e., stopping the biological activity of the bioactive molecule and also removing any unbound ligand. The presently pending claims, therefore, are beneficial over the prior art in that they remove the washing step and thereby simplify the assaying procedure. Since the Eibl et al. patent does not disclose the method of the presently pending claims, the claims are patentable over the Eibl et al. patent and reconsideration of the rejection is respectfully requested.

Claims 12, 14-18, and 20-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Behnke et al. patent. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Behnke et al. patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The presently pending claims have been amended to specifically recite that the probe is removed from a reaction vessel in order to stop the reaction. This is specifically set forth in the specification on page 7, lines 12-18, and page 13, lines 12 and 13, and throughout the specification. In the prior art reaction vessels, there was a required treatment step or washing step in order to stop the reaction. The benefit of the present invention is that there is no washing step required. All that is required is that the probe be removed from the reaction vessel and enzymatic activity can then be measured. The claims have been amended in order to further prosecution to recite that enzymatic activity is what is being measured. The prior art reference disclosed determining the presence of an antibody in a sample. There is no disclosure or suggestion in the prior art reference that the mere removal of the probe from the vessel is sufficient to stop the reaction. Instead, a further step is required, thereby necessitating further reagents to be utilized. The benefit of the present invention is that it simplifies all of the reactions required by only requiring that the probe be removed from the vessel. This is a benefit over the prior art and an improvement thereon.

The Office Action states that the Behnke et al. patent teaches a dipstick immunodisplacement device and method where an analyte in a sample displaces bound label from a specific binder bound to a solid phase, which is dipped into the vessel containing the sample. However, when read more specifically, the Behnke et al. patent discloses a much more complicated process. As set forth in column 5, lines 20-33, the process involves taking a test solution that contains a sample and another reaction partner and putting the solution in contact with one end of a test strip. The test solution is allowed to pass over at least one part of the test strip, including the partial area containing the antibody, by capillary migration. The test strip is subsequently washed and the test strip is brought into contact with a developing solution that contains members of a signal-generating system that are able to generate a detectable signal as a function of the amount of analyte in the sample and the partial area containing the antibody. This is in contradistinction with the method of the presently pending claims, which instead do not require a washing step. It was previously thought by those of skill in the art that washing was required in order to stop the reaction; i.e., stopping the biological activity of the bioactive molecule and also to remove any unbound ligand. The presently pending claims, therefore, are beneficial over the prior art in that they are able to remove the washing step and thereby simplify the assaying procedure. Since the Behnke et al. patent does not disclose the method of the presently pending claims, the claims are patentable over the Behnke et al. patent and reconsideration of the rejection is respectfully requested.

Reconsideration of the rejection under 35 U.S.C. §103 over Marquardt et al., Eibl et al., Fish et al. and Kohler et al. in view of Marquardt et al., Eibl et al., Fish et al. and Kohler et al. as applied to the present claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference. The presently pending claims have been amended to specifically recite that the probe is removed from a reaction vessel in order to stop the

reaction. This is specifically set forth in the specification on page 7, lines 12-18 and page 13, lines 12 and 13 and throughout the specification. In the prior art reaction vessels, there was a required treatment step or washing step in order to stop the reaction. The benefit of the present invention is that there is no washing step required. All that is required is that the probe be removed from the reaction vessel and enzymatic activity can then be measured. The claims have been amended in order to further prosecution to recite that enzymatic activity is what is being measured. The prior art references disclosed determining the presence of an antibody in a sample. There is no disclosure or suggestion in the prior art reference that the mere removal of the probe from the vessel is sufficient to stop the reaction. Instead, a further step is required, thereby necessitating further reagents to be utilized. The benefit of the present invention is that it simplifies all of the reactions required by only requiring that the probe be removed from the vessel. This is a benefit over the prior art and an improvement thereon.

The Office Action states that the Marquardt et al. patent teaches solid phase assays, both competitive and non-competitive, for bioactive substances, including enzymes and their inhibitors, essentially as instantly disclosed except for being performed in microtiter plates rather than on an insertable solid phase. However, as set forth in the present specification on page 2, lines 24-30, the method of the Marquardt et al. patent involves multiple steps including coating the wells of the microplate, washing the wells, adding biologically active substance to the wells, washing the wells once more, adding the indicator's enzyme to the wells, washing the wells again, and adding a colored development reagent. Therefore, this assay cannot be readily used in assays requiring rapid analysis and the method involves a multitude of steps as compared to the presently pending claims. Further, the Marquardt et al. patent requires a washing and development step. It is previously known to those of skill in the art that washing was required in order to stop the reaction; i.e., stopping the biological activity of the bioactive molecule and also to remove any unbound ligand. The presently pending

claims are an improvement over the prior art in that they are able to remove the washing step and thereby simplify the assaying procedures. Therefore, the Marquardt et al. patent does not disclose the method of the presently pending claims.

The Office Action states that the Eibl et al. patent discloses elongated elements such as "platelets" or pins, which are secured to a holding band in a carrier and that are insertable into the recesses of a microtiter plate containing samples to be assayed. Further, the Office Action states that various competitive assay formats are taught using an antigen or antibody bound to the elements and a labeled antigen or antibody added to the sample. Therefore, the Office Action concludes that the Eibl et al. patent teaches the carrier for the avoidance of complicated separating and washing procedures as are found in prior art assays performed with coated vessels, such as tubes. It is undisputed that the Eibl et al. patent discloses the use of elements that are secured to a holding band in a carrier that is insertable into the recesses of a microtiter plate containing samples to be assayed. However, when read more specifically, the Eibl et al. patent teaches an assay that utilizes "a solution of the radioactively labeled antibody is added to the sample to be examined for a content of antigen or antibody, and then a solid carrier loaded with unlabeled antigen is contacted with the sample liquid, whereupon after washing the carrier, the radioactivity of the carrier is measured." This is specifically set forth in column 2, lines 28-33, of the Eibl et al. patent. In other words, the Eibl et al. patent teaches an assay kit, but still requires a washing step in order to measure the radioactivity of the carrier. While the Eibl et al. patent discloses an assay kit with a decreased amount of steps required for performing the assay, it still requires washing procedures to be used in order for the assay to perform properly. This is in contradistinction with the method of the presently pending claims, which instead do not require a washing step. It was previously thought by those of skill in the art that washing was required in order to stop the reaction; i.e., stopping the biological activity of the bioactive molecule and also to remove

any unbound ligand. The presently pending claims, therefore, are beneficial over the prior art in that they are able to remove the washing step and thereby simplify the assaying procedure. Therefore, the Eibl et al. patent does not disclose the method of the presently pending claims.

The Fish et al. patent, according to the Office Action, teaches the general use of coated comb-like carriers for assays to detect binding of a variety of receptor-analyte pairs, such as enzyme-substrate, antibody-antigen, antigen-antibody, receptor-toxin, receptor-drug, or complementary nucleic acid pairs. However, when read more specifically, the Fish et al. patent again requires a washing step as found in the above described prior art patents. Specifically, the card of the Fish et al. patent must be developed in order to determine the presence of an analyte in each of the samples. The card is washed and then immersed in a second compartment and any additional compartments. This developing step is not required by the present invention nor do the presently pending claims recite use of a card for conducting the assay. Therefore, the Fish et al. patent does not disclose the method of the presently pending claims.

Finally, the Office Action states that the Köhler patent teaches a comb-like carrier coated with antigens or antibodies for immunological assays as an alternative to coated microtiter plates, using a microtiter plate only as a vessel for multiple samples. However, the Köhler patent discloses in column 2, line 67 through column 3, line 6, that the strips are treated with a reagent in conjunction with naphthol, which is subject to a color change as a result of the immunological reactions. The reaction result cannot otherwise be observed optically. Therefore, as with the above referenced prior art patents, there is a requirement that an additional washing or treatment step be performed in order for the assay to function properly. This is in contradistinction with the assay and method of the presently pending claims, which instead require that no washing step be used. Therefore, the Köhler patent does not disclose the assay and method of the presently pending claims.

In conclusion, the present application is in condition for allowance, which allowance is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Date: October 18, 2002

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on October 18, 2002.

Connie Herty

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

1. (Amended) A method for measuring [an activity or concentration of a biomolecule] enzymatic activity comprising:

providing a reaction vessel containing a sample, said sample including an enzyme [biomolecule] having an enzymatic [biological] activity;

providing a probe coated with a reactant coupled with a label, said reactant being capable of interacting with the [biomolecule] enzyme;

[adding a known quantity of a compound with a detectable label to the sample;]

inserting the probe into the reaction vessel such that the [biomolecule and the detectable label contact the reactant and] enzyme interacts with the reactant such that the label is [bound to the reactant] released into the vessel;

removing the probe from the reaction vessel, and stopping the reaction without a washing step; and

measuring a quantity of detectable label in the reaction vessel and/or on the probe, whereby the quantity of detectable label measures the activity or concentration of a biomolecule.